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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,352

02/27/2006

Albert Schomig

31698-1900

5048

71040

7590

07/11/2008

LUCE, FORWARD, HAMILTON & SCRIPPS  
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EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

07/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,352	<b>Applicant(s)</b> SCHOMIG ET AL.	
	<b>Examiner</b> SUBA GANESAN	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,21-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 4/17/2008 have been fully considered but they are not persuasive. Applicant argues that Sirhan lacks a metallic rate controlling element. This is not persuasive because Sirhan discloses a metal stent loaded with therapeutic agent (para 117). Additionally, this is not germane since rate-controlling features are not presently claimed.
2. Applicant further argues that Sirhan does not teach sandblasting. Examiner is considering sandblasting to be a product-by-process limitation, since the stent of Sirhan has a roughened surface, it meets the claim.
3. In response to applicant's argument that Thompson cannot be combined with Sirhan, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).
4. In response to applicant's arguments that Sirhan and Thompson teach away from an external rough surface, examiner disagrees because Sirhan teaches drug incorporation on both the external and luminal surfaces of a stent. Sirhan further teaches that a roughened surface increases the surface area for drug incorporation. Therefore it would have been an obvious conclusion to one of ordinary skill in the art at

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the time the invention was made to have the external and luminal surfaces roughened for drug incorporation.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "normal" in claims 29-30 is a relative term which renders the claim indefinite. The term "normal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and therefore one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-6, and 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (U.S. P.G. Pub. No.: 2002/0082679) in view of Thompson (U.S. Pat. No. 6,254,631).

3. Sirhan discloses a stent system comprising a stent with a roughened exterior surface for coating with a drug (para 177). The drug can be tacrolimus (para 30) and the stent is a stainless steel material (para 177). The stent is delivered using a balloon catheter (para 143). Sirhan is silent as to whether both surfaces of the stent are roughened. However, Sirhan teaches the use of therapeutic agent on both the outer and luminal surface of a stent (para 25) as well as roughening as a means for coating a metal surface with a drug (para 177). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided both the outer and luminal surfaces of a stent with a roughened surface for the purpose of providing therapeutic agents on the luminal and outer surfaces.

4. Sirhan does not appear to disclose roughening the side surfaces in addition to the exterior stent surface. Thompson teaches the use of roughened inner and side stent surfaces (see abstract and fig. 4) for the purpose of preventing relative motion between the stent and the delivery balloon (col. 3 lines 10-46). Therefore it would have been obvious to one of ordinary skill in the art to modify the stent of Sirhan to include roughened inner and side surfaces as taught by Thompson for the purpose of allowing the stent to better grip the delivery balloon.

5. Sandblasting with sand, glass beads, or corundum is considered a product-by-process limitation that is not given patentable weight in the absence of distinguishing structure (See MPEP 2113).

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

Examiner, Art Unit 3774

/William H. Matthews/

Primary Examiner, Art Unit 3774